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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,909	01/17/2002	Timothy G. Helentjaris	BB1163 US CIP	3323
27123	7590	04/25/2005	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,909	Applicant(s) HELENTJARIS, TIMOTHY G.	
	Examiner Hope A. Robinson	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☒ Claim(s) 1-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>4/13/05</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

20

DETAILED ACTION

Application Status

1. The Non-responsive communication mailed on March 31, 2005 has been vacated in favor of the following office action.
2. The Finality of the previous office action mailed on October 20, 2004 has been withdrawn in view of the present rejoinder.
3. The Restriction Requirement set forth on November 19, 2003 has been withdrawn as claim 11 has been rejoined. Applicant was notified in the office action mailed on October 20, 2004 and telephonically on April 13, 2005 that patentability issues would be raised by rejoinder of process claim 11. Applicant has chosen to prosecute the rejoined claim.
4. The Amendment filed on September 28, 2004 has been received and entered.

Claim Disposition

5. Claims 12-19 have been cancelled. Claims 1-11 are pending and are under examination.
6. The following grounds of objection/rejection are or remain applicable:

Specification

7. The specification is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TRIS[®]-HCL, for example, have been noted in this application (see page 36). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that the specification is amended to delete "Tris-HCl" for example, and insert " TRIS[®] HCL (hydroxymethyl) aminomethane hydrochloride".

Correction of the above is required.

Sequence Compliance

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, page 29, lines 24-25. If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof,

Art Unit: 1653

applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

Claim Objection

9. Claim 1 is objected to because of the following informalities:

For clarity and precision of claim language, claim 1 (a) should be amended to recite "a nucleotide sequence encoding a polypeptide having sugar transport protein activity, wherein said polypeptide is at least 91% identical to SEQ ID NO: 32 or 36". In addition, for clarity and precision of claim language, claim 1 (b) needs to recite a function because item (b) cannot encode the protein of item (a) or the claim should be amended to recite "full complement".

Correction of the above is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide encoding a sugar transport protein from *Arabidopsis*, does not reasonably provide enablement for a method for producing a plant comprising transforming a plant cell with said polynucleotide and regenerating the plant from the transformed plant cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass any plant of any species, for example: oak, pine, apple, tomato, orchid, rice etc. which are unrelated and wherein plant transformation might be difficult to achieve. The claim also encompasses any phenotype. The specification does not describe or demonstrate the

Art Unit: 1653

claimed *Arabidopsis* polynucleotide used to produce any plant and to regenerate any plant from the transformed plant cells or demonstrate all possible phenotype. The examples provided in the instant specification are prophetic and thus, one of skill in the art would have to engage in undue experimentation to practice the claimed invention.

The instant specification does not demonstrate or provide guidance for obtaining any phenotypic change in *Arabidopsis*, the source of the sugar transporter gene disclosed in the instant specification, let alone any other plant species encompassed by the claim. Thus, due to the large quantity of experimentation necessary to generate the infinite number of plants from different species recited in the claims and possibly screen same for the desired effect and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

The state of the prior art provides evidence for the high degree of unpredictability in obtaining desired or expected phenotypes following plant transformation with genes encoding proteins involved in carbohydrate metabolism, particularly when genes from one plant source are introduced into a plant of a different source. For example, Kull et al. (J. Genet. And Breed, vol. 49, no. 1, pages 69-76, 1995) teach that antisense GBSSI (granule-bound starch synthase) sequences from barley had no effect on the degree of branching of starch produced by potato plants transformed therewith (see page 69, Abstract). In addition, the art recognizes that even when a plant is transformed from a certain species with a carbohydrate metabolism gene from the same species, the desired phenotypic change might not result (see Kossmann et al., Progress

in Biotechnology, vol. 10, pages 271-278, 1995). Further, the working examples provided do not rectify the missing information in the instant specification. Thus, the nature and properties of this claim is difficult to ascertain from the examples provided.

The specification does not provide support for the broad scope of the claim, which encompasses any plant of any species and any phenotype. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to produce or regenerate plants of any species and any phenotype of the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use

Art Unit: 1653

the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Conclusion

11. No claims are presently allowable.

12. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

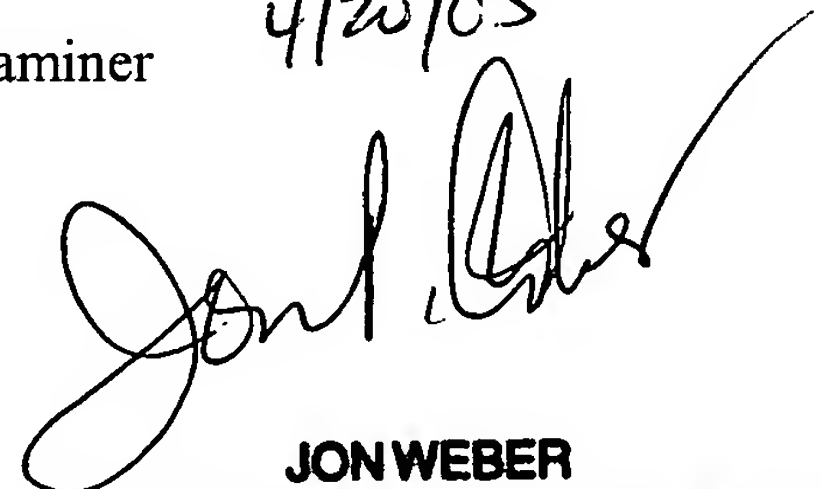
Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS *HR*

Patent Examiner

4/20/05

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, sweeping flourish extending from the end of the name.

JON WEBER
SUPERVISORY PATENT EXAMINER